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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,711	07/27/2001	Rathbun Rhodes	1146-8	8240

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EXAMINER	
NASSER, ROBERT L	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,711	RHODES ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-15 and 21-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-15 and 21-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1 121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/16/05, 8/4/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Look at claims 25-28- maybe make obvious.

Make final

Cite McIvor et al 6520326

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 21, 24, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito 5,384,028. In figure 2, Ito shows a biosensor with a sapphire (glass) housing, substrate 11, a working electrode 13, a counter electrode 12, and a reference electrode 14, where the counter electrode has a larger area than the working electrode, and a multi-region membrane, a lactate-oxidase membrane on the working electrode and a albumin membrane on the other electrodes. The examiner notes that the electrode of Ito is "configured for implantation" in that it is capable of being implanted. As to claim 29, Ito measures glucose or lactate in a biological fluid.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5-10, 12-15, and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al 6392161 in view of Shults et al 6001067 and Nagata 4871440. Heller et al shows an electrode 2 under a mutli-layered membrane 8, 10, 12, and 1. In column 7, lines 65-column 8, line 17, Heller et al states that it can make glucose measurements by monitoring the rate of change of current in an electrode system and states that a reference and a counter electrode are necessary for such a measurement. Heller et al does not show the structure of the three-electrode system. However, Shults et al shows such a three electrode glucose sensing device that includes a housing made from polyethylene, (see column 9, lines 35-36), where the housing includes a sensing area having a working reference and counter electrode 20, 21, and 22, and a multi-layer membrane over the electrode area. It would therefore have been obvious to modify Heller et al to use the structure of Shults, as it is merely the substitution of one known equivalent structure for another. The areas of the counter and working electrodes appear to be the same. However, Nagata et al shows a 3-electrode system for measuring glucose concentration, where the counter electrode is made larger than the working electrode (see figures 9 and 10) to stabilize the potentials of the electrodes. Therefore, it would have been obvious to modify the above combination to use such an arrangement of working and counter electrodes, so as to stabilize the potential of the electrodes. The examiner notes that Nagata does not disclose the relative sizes of the electrodes. However, based on the nature of use of

the device, it is the examiner's position that it would have been obvious to make the relative sizes be about within the claimed ranges. In Shults, the multi-layer membrane includes (from farther away to adjacent to electrodes) an angiogenic layer which is equivalent to the disclosed cell disruptive domain, a second layer which is the bioprotective layer, which is equivalent to the cell impermeable domain, then an enzyme membrane comprised of a resistance layer, an enzyme layer, an interference layer, and a electrolyte (i.e. hydrogel layer). The examiner notes that with respect to claim 6, the first domain of Shults is the angiogenic layer and the bioprotective layer. With respect to claim 7, the resistance layer of Shults is the second domain and excludes glucose. With respect to claims 8 and 9, the enzyme layer of Shults is the third domain. Both the working and counter electrodes are made from platinum (see column 9, line 62- column 10, line 2). The device of Shults is implanted. Shults further teaches the recited method.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al in view of Shults et al and Nagata as applied to claims 1, 2, 5-10, 12-15, and 22-33 above, and further in view of Schulman et al 6119028. Shults does not teach a material for the resistance layer. However, Schulman shows a membrane 24 that behaves in the same manner of the resistance layer. Membrane 24 of Schulman is made from silicone, which is disclosed to be the material used for the oxygen antenna domain. Hence, it would have been obvious to modify the above combination to make the resistance layer from silicone, as it is merely the substitution of one known material

for another. Hence, membrane 24 is an oxygen antenna. With respect to claim 7, membrane 24 of Shults is a glucose exclusion membrane

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al in view of Shults et al and Nagata et al as applied to claims 1,2, 5-10, 12-15, and 22-33 above, and further in view of Ward et al 6,212,416. Ward et al shows an analyte sensing device with a ceramic housing. Hence, it would have been obvious to modify the above combination to use ceramic, as it is merely the substitution of one known equivalent material for another.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

McIvor et al 6360888 shows in figure 15 an electrode arrangement where the counter electrode is bigger than the working electrode for glucose sensor. Applicant should consider this reference when responding to this office action.

Applicant's arguments filed 3/22/2005 have been fully considered but they are not found to be persuasive.

Applicant has asserted that Ito is not "configured for implantation in a host" or for "subcutaneous implantation." The examiner notes that this in an intended use limitation. Applicant cannot distinguish over identical structure based on how the structure is used. Here, the device of Ito can indeed be implanted in a host.

With respect to the Heller/Shults combination, applicant has asserted that Heller is concerned with size while Shults is not and therefore to substitute the sensor of Shults into the device of Heller would render the device unsuitable for its intended use. The examiner notes that nowhere did the examiner say that the sensor of Shults should be bodily substituted as is into the device of Heller. Indeed, the Federal Circuit has established that the references need not be bodily combined. Rather, the Federal Circuit has further established that reference is good for all it teaches. Here, it is the examiner's position that Shults shows the structure of a three electrode system. There is no evidence of record stating that the device of Shults would not function if it were made smaller. As such, one skilled in the art, based on the size limitations of Heller, would clearly recognize that the sensor would have to be designed subject to the teachings of Heller.

Applicant has asserted that oxygen needs to be limited in the system of Heller and that using the larger electrode of Nagata would result in poorer performance. However, there is no evidence of record to support these assertions. Clearly, applicant cannot establish a lack of motivation to combine based on unsupported allegations.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
June 13, 2005